

REMARKS

The Official Action dated July 3, 2001 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 1 is amended to recite that the one or more ABPA-related recombinant allergens discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*, as set forth in the specification, for example at page 15, lines 3-13 and Table 4 at page 24. Claims 4, 5, 16 and 18 have been amended to stand in independent form and claims 17 and 19 have been amended to change their dependency. A Version With Markings Showing Changes Made is attached. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, the Examiner indicated that claims 4, 5, 10-13 and 15-20 are free of the prior art as of the last search. As claims 4, 5, 16 and 18 have been rewritten to stand in independent form, Applicants submit that claims 4, 5, 10-13 and 15-20 are now in condition for allowance. Reconsideration is respectfully requested.

Claims 1-3, 6-9 and 14 were rejected under 35 U.S.C. §103 as being unpatentable over the Little et al publication entitled "Improved Diagnosis of Allergic Broncopulmonary Aspergillosis With gp66 (Formerly Antigen 7) of *Aspergillus fumigatus* for Specific IgE Detection." The Examiner asserted that the claimed invention differs from the prior art teachings only by the recitation that the claimed ABPA-related allergen is recombinant. The Examiner relied on *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172 (USPTO Brd. of Pat. App. and Int. 1995) to conclude that real world workers in the field of molecular biology are clearly

motivated to determine the nucleotide sequences that code for such proteins so that increased quantities of the proteins may be produced through recombinant DNA technology.

However, Applicants submit that the methods defined by claims 1-3, 6-9 and 14 are nonobvious over and patentably distinguishable from Little et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

According to claim 1, the invention is directed to methods for the diagnosis of ABPA in a human individual. The methods comprise determining if the individual carries antibodies reactive with one or more ABPA-related recombinant allergens which discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*.

The Little et al publication is discussed in the present specification at page 3, lines 14-18. Little et al describe the use of gp66 (formerly antigen 7) to screen for *A. fumigatus* proteins for allergenic activity by crossed radioimmuno-electrophoresis. However, as noted in the specification, the glycoprotein gp66 of Little et al does not allow for differential diagnosis of ABPA because it reacts with sera of *A. fumigatus*-sensitized patients without ABPA and sera of ABPA patients. That is, the glycoprotein of Little et al does not discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*. On the other hand, the methods according to claim 1 employ one or more ABPA-related recombinant allergens which discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*. Little et al provide no teaching or suggestion in this regard. Thus, Little et al do not render the present methods obvious.

Moreover, Applicants respectfully submit that *Ex parte Goldgaber, supra*, is not relevant to the patentability of the presently claimed methods. That is, not only did the *Goldgaber* Board acknowledge that each case under 35 U.S.C. §103 is decided on its own particular facts, 41 U.S.P.Q.2d 1172, 1176, the Board clearly emphasized that the prior art relied upon by the Examiner and the Board disclosed the extraction, purification and amino

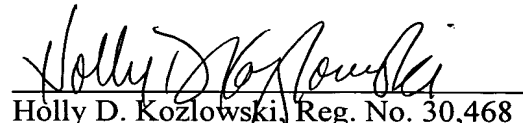
acid sequencing of the subject polypeptide together with the gene coding and the DNA or mRNA coding for the subject polypeptide, 41 U.S.P.Q.2d at 1173-1174. Applicants find no such teachings by Little et al. Thus, the Examiner's conclusion that a recombinant form of the Little et al protein would have been obvious is not supported by the teachings of Little et al.

References relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). In view of the failure of Little et al to teach or suggest one or more ABPA-related recombinant allergens which discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*, Little et al do not provide an enabling disclosure of the presently claimed methods and therefore do not place the claimed invention in the possession of the public. Thus, Little et al do not support a rejection of claims 1-3, 6-9 and 14 under 35 U.S.C. §103.

It is therefore submitted that the methods defined by claims 1-3, 6-9 and 14 are nonobvious over and patentably distinguishable from Little et al, whereby the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejection under 35 U.S.C. §103, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,


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VERSION WITH MARKINGS SHOWING CHANGES MADE

1. (Third Amendment) A method for the diagnosis of ABPA in a human individual, comprising determining if the individual carries antibodies reactive with one or more ABPA-related recombinant allergens, which one or more ABPA-related recombinant allergens discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*.

4. (Third Amendment) [The method according to claim 1,] A method for the diagnosis of ABPA in a human individual, comprising determining if the individual carries antibodies reactive with one or more ABPA-related recombinant allergens, which one or more ABPA-related recombinant allergens discriminate between ABPA and allergic sensitization to *A. fumigatus* and wherein the one or more allergens are selected from the group consisting of rAsp f4 and rAsp f6, and ABPA-related fragments thereof which bind with IgE or IgG antibody.

5. (Third Amendment) [The method according to claim 1,] A method for the diagnosis of ABPA in a human individual, comprising determining if the individual carries antibodies reactive with one or more ABPA-related recombinant allergens, which one or more ABPA-related recombinant allergens discriminate between ABPA and allergic sensitization to *A. fumigatus* and wherein the one or more allergens are selected from the group consisting of rAsp f8 and ABPA-related fragments thereof which bind with IgE or IgG antibody.

16. (Twice Amended) [The method according to claim 2] A method for the diagnosis of ABPA in a human individual, comprising determining if the individual carries

antibodies reactive with one or more ABPA-related recombinant allergens, which one or more ABPA-related recombinant allergens discriminate between ABPA and allergic sensitization to *A. fumigatus*, wherein the allergen is derived from *A. fumigatus* and wherein the one or more allergens are selected from the group consisting of rAsp f4 and rAsp f6, and ABPA-related fragments thereof which bind with IgE or IgG antibody.

17. (Twice Amended) The method according to claim [1] 16, wherein the one or more allergens are selected from the group consisting of rAsp f4 and rAsp f6.

18. (Twice Amended) [The method according to claim 2,] A method for the diagnosis of ABPA in a human individual, comprising determining if the individual carries antibodies reactive with one or more ABPA-related recombinant allergens, which one or more ABPA-related recombinant allergens discriminate between ABPA and allergic sensitization to *A. fumigatus*, wherein the allergen is derived from *A. fumigatus* and wherein the one or more allergens are selected from the group consisting of rAsp f8, and ABPA-related fragments thereof which bind with IgE or IgG antibody.

19. (Twice Amended) The method according to claim [1] 18, wherein the allergen is rAsp f8.

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